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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,277	08/20/2001	Peter Jozef Leo Hespel	702-010802	6608

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,277

Applicant(s)

HESPEL, PETER JOZEF LEO

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Request for Continued Examination and Amendments received January 14, 2005 is acknowledged. Claims **13-18 and 21-22** are pending in this application. Claims 1-12 and 19-20 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 has been amended to recite “temporary” immobilization and applicant cites page 1, lines 29-31 for support. However, this recitation is considered new matter since purported support does not provide the general concept of temporary. The instant specification neither uses the terminology temporary nor alludes to it. Further, the specification does not define the metes and bounds of temporary.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 13-18 and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "temporary" in claim 13 is a relative term, which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Further, claim 18 recites, "wherein the muscle disuse syndrome is the result of reduced physical activity due to immobilization, disease, aging, or handicap." It is unclear how aging, disease, and handicaps are considered temporary immobilization.

Further, clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/00148 (entire translated document).

WO teaches the administration of creatine for the therapeutic use of improving muscle mass, muscle function, muscle stamina, shortening the recovery after physical strain after post-operative muscle atrophy, treatment of heart complaints, different types of myopathy and cachectic states. See abstract and especially claim 9. WO teaches that creatine may be supplied in a dosage of 50mg to 10 grams per day, 50 mg to 5 grams per day wherein the dosage may be administered in one single application or in two or three applications per day. See page 7 of translation. Additionally, WO teaches that the optimal dosage depends on the particular use, the body weight, the age, and individual conditions of the patient. See page 12. WO discloses an example wherein a total daily dose of 9 grams of creatine, three times a day, is provided for one week; followed by a maintenance dose of 3 grams of creatine in a unit dose once a day for five weeks. See page 13 of translation. Note that the maintenance dose reads on the instant rehabilitation period.

Although, WO teaches the instant total daily supplement of creatine and administering the creatine dosage in several applications throughout the day, WO does not specify utilizing about 5 grams per application for the immobilization period. Further, although WO teaches administering 3 grams creatine once daily for the maintenance dose, WO does not teach the instant 5 grams.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by WO and manipulate the dosage parameters. Firstly, it is the examiner's position and absent evidence demonstrating otherwise, that the criticality lies in the

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total daily dose. Thus, since WO teaches instant total daily dosage and teaches that the daily dose may be divided in two or three doses within a given day, determining the amount in which the daily dose is divided is obvious. The amount per application depends on the total amount of creatine to be administered for the day and the number of divided doses one desired to administer, i.e. providing two applications or three applications per day of the total.

Secondly, it is pointed out that the recitation of “about” permits some tolerance of about ± 10 degrees. *In re Ayers*, 154 F 2d 182, 69 USPQ 109 (CCPA 1946). Therefore, the prior art’s administration of 3 grams creatine per dose in the first phase, followed by administration of 3 grams once in the maintenance phase, is an obvious parameter of instant recitation “about 5 grams”.

Lastly, one would have been motivated to manipulate the dosage amount of 3 grams to instant 5 grams since as taught by WO optimal dosage amounts depend on an array of factors such as patient profile, which includes weight, age, symptoms, severity of symptoms, and disease being treated. Therefore, it is within the skill of an artisan to determine and provide the appropriate dosage through routine experimentation and optimization.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection, i.e. WO is no longer said to anticipate the instant invention. However, since the examiner has maintained WO has a reference, the merits of WO will be discussed.

Applicant argues that WO argues that the applicant has amended the claims to recite “temporary immobilization” and therefore overcomes WO’s method of treating muscle atrophy.

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Applicant argues that muscle atrophy is only one of the factors that characterize muscle disuse syndrome. It is further argued that muscle disuse syndrome is different from muscle atrophy, muscle dystrophy, etc.

Firstly, it is pointed out that “temporary” has been rejected as a new matter and under indefiniteness.

Secondly, as acknowledged by the applicant and as disclosed by the instant specification on page 1, muscle atrophy is a symptom of muscle disuse syndrome. WO clearly teaches shortening the recovery phase of physical stress after post-operative muscle atrophy....etc. See claim 9. Therefore, the treatment of even one symptom of a disease, i.e. muscle atrophy, is treatment nonetheless. Moreover, the instant specification further characterizes muscle disuse with reduced energy stores and muscle fatigue. WO further teaches building skeleton muscle tone, improving physical performance, capacity, and endurance by administering creatine. Thus, WO again teaches treating other symptoms of muscle disuse syndrome.

Additionally, the examiner points out that the preamble recites “a method of the treatment of skeletal muscles subjected to temporary immobilization which results in muscle disuses syndrome”. Therefore, if one is suffering from post-operative muscle atrophy, it will result in muscle disuse.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

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